K022962

NOV 1 2002

Wiener lab.
Especialidades para Laboratorios Clínicos

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Section 6 – Summary

510(k) Summary
"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92"

"The assigned 510(k) number is: _____"

Introduction

According to the requirements of 21 CFR 862.1110, the following information provides sufficient details to understand the basis of a determination of substantial equivalence.

6-1 Submitter Name, Address, Contact

Wiener Laboratorios S.A.I.C.
Riobamba 2944
2000 – Rosario – Argentina
Tel: 54 341 4329191
Fax: 54 341 4851986
Contact person: Viviana Cétola
Date Prepared: July 07, 2002

6-2 Device Name

Proprietary name: Wiener lab. BILIRRUBINA TOTAL AA

Common name: Bilirubin (total) test system

Classification name: Diazo colorimetry, Bilirubin Device Class II, CIG, as per 21 CFR section 862.1110.

Device Class II

6-3 Predicate Device

We claim substantial equivalence to the currently marketed DMA Total Bilirubin Plus test system (Cat. Nº 1245).

6-4 Device Description

Total bilirubin (both conjugated and free) is measured using a stable dichlorophenyl diazonium salt (DPD) to form an azobilirubin compound with maximal O.D. at 546 nm. Surfactants are used as reaction accelerators.

The amount of bilirubin is determined by measuring the absorbance of this pigment.

6-5 Intended Use

The WIENER LAB. BILIRRUBINA TOTAL AA test system is a quantitative in vitro diagnostic device intended to be used in the quantitative determination of total bilirubin in human sera and heparinized plasmas on both manual and automated systems. Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder block.

6-6 Equivalencies and Differences

The WIENER BILIRUBIN TOTAL AA test system is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed DMA Total Bilirubin Plus test system.

The following table illustrates the similarities and differences between the WIENER BILIRUBIN test system and the currently marketed DMA Total Bilirubin Plus test system.

	DMA Test System	**WIENER LAB. Test System**
Intended Use	Quantitative determination of total bilirubin in human serum and EDTA or heparinized plasma.	Quantitative determination of total bilirubin in human serum and heparinized plasma.

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	DMA Test System	WIENER LAB. Test System
Test Principle	Total bilirubin (both conjugated and free) is measured using a stabilized diazonium salt of 3,5-dichloroaniline which reacts with bilirubin to form azobilirubin with maximum absorbance at 540 nm. Surfactants are used as reaction accelerators.	Total bilirubin (both conjugated and free) is measured using a stable dichlorophenyl diazonium salt (DPD) to form an azobilirubin compound with maximal O.D. at 546 nm. Surfactants are used as reaction accelerators.
Reagents	Reagent: 3,5-dichlorophenyldiazonium tetrafluoroborate and surfactants.	R1: hydrochloric acid and surfactant. R2: dichlorophenyl diazonium salt. Reagent for sample blank: hydrochloric acid and surfactant.
Preparation of Working Reagent	Ready to use	Reconstitute each Reagent 2 vial with stated volume of Reagent 1.
Stability of Final Color	60 minutes at room temperature (15-30ºC)	30 minutes at room temperature
Wavelength of Reading	540 nm	546 nm
Calibration	Single point	
Linearity	20 mg/dl	
Expected values	0.0 – 1.5 mg/dl	- Adults: up to 1.0 mg/dl - Newborns: ranging from 2.0 to 16 mg/dl depending on birth condition (full term or premature) and days of life.

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	DMA Test System	WIENER LAB. Test System
Within-run precision	Low Serum Control: CV = 5.00% Moderate Serum Control: CV = 2.20% High Serum Control: CV= 1.56%	Normal Level Serum: CV = 1.50% High Level Serum: CV = 0.98%
Run-to-run precision	Low Serum Control: CV = 6.40% Moderate Serum Control: CV = 0.83% High Serum Control: CV= 2.10%	Normal Level Serum: CV = 2.68% High Level Serum: CV = 1.08%

6-7 Conclusion Above mentioned data show substantial equivalency to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 1 2002

Dr. Viviana Cetola
QC/QA Manager
Wiener Laboratorios S.A.I.C.
Riobamba 2944
2000 Rosario, Santa Fe
Argentina

Re: k022962
Trade/Device Name: Wiener Lab Bilirrubina Total AA
Regulation Number: 21 CFR 862.1110
Regulation Name: Bilirubin (total or direct) test system
Regulatory Class: Class II
Product Code: CIG
Dated: August 30, 2002
Received: September 6, 2002

Dear Dr. Cetola:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022962

Device Name: Wiener lab.
Bilirrubina Total AA

Indications For Use:

The "Wiener lab. Bilirrubina Total AA" test system is a quantitative in vitro diagnostic device intended to be used in the quantitative determination of total bilirubin in human sera and heparinized plasmas on both manual and automated systems. Measurements of the levels of bilirubin, an organic compound formed during the normal and abnormal destruction of red blood cells, are used in the diagnosis and treatment of liver, hemolytic, hematological, and metabolic disorders, including hepatitis and gall bladder block.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(K) Number K022962

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)